Exhibit B
Part 3 of 3

regulations in order for the state to qualify for federal financial participation payments. The Secretary of HHS must review and approve each state's plan.

B. Medicaid Drug Rebate Program

124. The Medicaid Drug Rebate Program was established by Congress with the passage of the Omnibus Reconciliation Act of 1990 (OBRA '90). This drug rebate program began operation January 1, 1991. Congress enacted the OBRA '90 Medicaid Drug Rebate Program because "States were not able to address the primary cause of escalating program costs—steep increases in drug prices at the product level—because drug manufacturers would not negotiate lower prices with Medicaid programs."[13]

125. To enable the states to address manufacturer drug prices, Congress designed the Medicaid Drug Rebate Program "to offer Medicaid the prices that they (drug manufacturers) were giving to their best customers, or their "best price.""[14] In other words, this legislation was intended to provide the governmental drug program with the economic benefit of market-based prices similar to those available to the best non-governmental drug purchasers. Congress also expected the Medicaid Drug Rebate Program to allow "expansion of Medicaid benefits . . . being constrained by budget limits on federal and state spending for social programs."[15]

126. By reducing the net drug expenditures of the state, the advent of the Medicaid Drug Rebate Program in 1991 enabled states to extend coverage to a larger population and to expand the number of prescriptions dispensed. State Medicaid programs have enlarged the number of beneficiaries and thus increased access to prescription drugs

[13] Pollard, Michael R. and Coster, John M., "Update I. Legislation. Savings for Medicaid Drug Spending," *Health Affairs*, Summer 1991, pp. 196-206.
[14] Pollard and Coster, *Health Affairs*, Summer 1991, pp. 196-206.
[15] Pollard and Coster, *Health Affairs*, Summer 1991, pp. 196-206.

through this government financed and subsidized program. This government drug program has provided access to prescription drugs for many people who could not have afforded their drugs before, thus increasing total sales for drug manufacturers.

127. Drug firms must voluntarily agree to participate in the Medicaid Drug Rebate Program in order to have their drug products covered by the Medicaid program. For those who voluntarily participate in the drug rebate program, reporting of their drug product prices (i.e., AMP and best price) is required. Manufacturers chose to participate in the drug rebate program and to report the required price information in order to have their drug products covered by the state Medicaid programs, because otherwise they realized that they would lose a substantial amount of sales. The average manufacturer price (AMP) is based on the weighted average of the aggregate sales revenue received by the manufacturer and divided by the aggregate units sold.

128. Because the Medicaid drug program paid for approximately 10% to 15% of outpatient drug purchases in this country, the failure of a manufacturer to participate in the Medicaid Drug Rebate Program would likely have affected the purchasing decisions of pharmacies. For most generic drug products, a pharmacy typically likes to purchase only one manufacturer's drug product and if that drug manufacturer does not participate in Medicaid, the pharmacy would have to stock a second manufacturer's drug product. Instead, the pharmacy would only purchase generic drug products from manufacturers that were participating in the Medicaid drug rebate program to avoid having a duplicate inventory and the increased inventory carrying cost.

129. The Secretary of HHS has authority to terminate manufacturers and their drug products from coverage in Medicaid if the manufacturer fails to participate in the

Medicaid Drug Rebate Program (Social Security Act, § 1927(b)(4)(B)). The rebate agreement obligates the drug manufacturer to report to CMS its AMP and, if applicable, its best price for each drug product (by NDC number) on a quarterly (i.e., four times a year) basis. State Medicaid programs then have to report to CMS, and each participating drug manufacturer, the quantity of each drug product (by NDC) paid for by the state's Medicaid program in a given quarter. This unit volume is multiplied by the Unit Rebate Amount (URA) provided by CMS to the states to calculate the amount of rebate due based on the rebate formulae specified in federal statute.

130. Simplistically, drug firms selling single source (patented brand) drug products or innovator multiple source (off-patent brand) drug products must pay a rebate which is the greater of: (1) 15.1 percent of the AMP; or (2) the AMP less the best price offered to certain classes of trade. In addition, an inflation adjustment rebate factor is also due. Non-innovator multiple source (off-patent generic or non-originator brand) drug products pay a fixed percentage rebate of 11% of AMP. These generic drug products are not subject to either the best price calculation or the inflation adjustment rebate.[16]

131. If manufacturers report inflated prices (AWP, WAC or DP) used for Medicaid reimbursement or report false and misleading AMPs or best prices (BPs) used for calculating Medicaid rebates, the amount of rebate received by the Medicaid Drug Rebate Program does not, in fact, result in Medicaid programs receiving manufacturer rebates that reduce the ultimate drug cost to a point equivalent to the cost of the manufacturers' best non-governmental customers.

[16] National Pharmaceutical Council, *Pharmaceutical Benefits Under State Medical Assistance Programs, 2007*, pp. 4-24.

132. As noted earlier, the Medicaid Drug Rebate Program was intended to enable states to address "the primary cause of escalating program costs—steep increases in drug prices at the (drug manufacturer) product level."[17] This rebate program was not intended to reduce pharmacy reimbursement under Medicaid "[b]ecause states had made pharmacy reimbursement a primary focus of their Medicaid drug program cost containment efforts in the 1980s."[18] For this reason, the rebate program was designed to be entirely separate from the pharmacy reimbursement program and to prevent Medicaid programs from further cutting pharmacy reimbursement. In fact, "Congress sought to limit cuts in this area by seeking a freeze on state pharmacy reimbursements."[19]

133. I have been asked to provide an opinion on the following statement of Dey, which Roxane also expressly adopted: "The Government's entitlement to receive Dey's AMP information, therefore, vitiates the reliance element of the Government's common law fraud claim because the Government had access to the allegedly missing "far lower price" information." (Dey Defendants' Memorandum of Law in Support of Their Motion to Dismiss The United States' Complaint, *U.S. ex rel. Ven-A-Care v. Dey*, December 12, 2006, pp.22-23; see also, Roxane's Memorandum of Law in Support of Its Motion to Dismiss The United States' Complaint, *U.S. ex rel. Ven-A-Care v. Roxane*, March 22, 2007, p.5, footnote 2].

134. This statement by Dey and Roxane is inconsistent with Medicaid statutes, regulations, policies, and practices. First, the statutes did not allow any other use of the AMP and best price data other than calculation of the unit rebate amounts under the Medicaid drug rebate program. Second, the unit rebate amounts provided to the states by

[17] Pollard and Coster, *Health Affairs*, Summer 1991, pp. 196-206.
[18] Pollard and Coster, *Health Affairs*, Summer 1991, pp. 196-206.
[19] Pollard and Coster, *Health Affairs*, Summer 1991, pp. 196-206.

CMS under the drug rebate program cannot usually, or reliably, be reverse engineered to determine the AMP. Third, even if the statute did not prohibit disclosure or use of AMP, or if determination of the AMP could be reverse engineered by the states, the use of AMP as a basis for reimbursement is not practical for other reasons.

135. First, the statutes did not allow any other use of the data other than calculation of the unit rebate amounts under the Medicaid drug rebate program. Until recently, when the Deficit Reduction Act of 2005 (DRA) was passed, the Medicaid rebate statute which defines AMP and its use specified that the AMP information provided by manufacturers "shall not be disclosed by the secretary . . . or a State agency . . . except as the secretary determines to be necessary to carry out this section." [42 U.S.C. § 1396r-8(b)(3)(D)]. As a result of this statute the Secretary did not give the states the AMP data for specific prescription drugs. [*See* Medicaid Program: Payment for Covered Outpatient Drugs Under Drug Rebate Agreements With Manufacturers, 60 Fed. Reg. 48442, 48475 (Sept. 19, 1995) (preface to the proposed rule in 1995 expressly discussing Secretary's limitation on access to AMP data by the states)]. In a hearing before Congress, the Secretary of HHS publicly expressed the view that HHS was not permitted to use the AMP data for Medicare reimbursement. [*See* "Reimbursement and Access to Prescription Drugs Under Medicare Part B," 107th Cong. 16, Hearing Before the Subcomm. On Health Care of the S. Finance Comm., March 14, 2002, Statement of Thomas A. Scully, 2002 WL 399357].

136. The State of Texas specifically requested clarification from CMS as to whether or not states could use rebate program information to calculate an estimated

acquisition cost (EAC) for (pharmacy) reimbursement.[20] The reply from CMS clearly re-stated the issue as: "First, you ask for confirmation that State Medicaid programs may not use the rebate information, including the Unit Rebate Amount (URA) and Reconciliation of State Invoice (ROSI) reports, to calculate an estimated acquisition cost (EAC) for (pharmacy) reimbursement."[21] The CMS answer was also clear and direct: "You are correct."[22]

137. Various state Medicaid agency personnel have testified that they were well aware that the Medicaid rebate information (i.e., URAs and AMPs) was confidential and could not be used for reimbursement purposes. For example, Ms. Farrand, the New Hampshire Department of Health and Human Services designee, clearly understood that the URA data provided to states was not to be used for reimbursement purposes and that the data was confidential and not to be disclosed. (Lise Farrand, Pharmaceutical Services Specialist, State of New Hampshire, Department of Health and Human Services, deposed in *U.S. ex rel. Ven-A-Care v. Dey et al.*, October 28, 2008, pp. 226, 287-293; see also deposition of Margaret Clifford, Pharmaceutical Services Specialist, State of New Hampshire, Department of Health and Human Services, from 1994 through 2000, *U.S. ex rel. Ven-A-Care v. Dey et al.*, October 29, 2008, pp. 196-230). According to Kevin Gorospe of MediCal (California) all URA information is held confidential and the state realizes that if it were to utilize the rebate information for reimbursement, such a use would breach the confidentiality restrictions. (J. Kevin Gorospe, *California v. Abbott Laboratories*, December 3, 2008, pp. 286-287; see also, James Parker (IL), *U.S. ex rel.*

[20] Letter from Patrick J. O'Connell, Assistant Attorney General, Office of the Attorney General, State of Texas to Mr. Dennis Smith, Director, Center for Medicaid State Operations, CMS, re: Request for Information from State of Texas, dated March 31, 2003.
[21] Letter from Patrick J. O'Connell, State of Texas to Mr. Dennis Smith, CMS, March 31, 2003.
[22] Letter from Patrick J. O'Connell, State of Texas to Mr. Dennis Smith, CMS, March 31, 2003.

Ven-a-Care v. Abbott Lab, Inc., 06-11337-PBS, Nov. 18, 2008, pp. 72-74; and Suzette Bridges (AR), *U.S. ex rel. Ven-a-Care v. Abbott Lab, Inc.*, 06-11337-PBS, Dec. 10, 2008, pp. 70-72.)

138. The Medicaid agency designee for the State of Washington also understood that the URAs provided to the state by CMS were not to be disclosed and were not to be used as the basis for reimbursement. (e.g., see Ayuni Hautea-Wimpee, *U.S. ex rel. Ven-A-Care v. Abbott Laboratories et al.*, November 24, 2008, pp. 594, 606-608). The Director of the Department of Human Services, State of Hawaii, in a State Plan Amendment memo to HCFA noted, "The State will keep the unit rebate amount confidential and will not disclose it for purposes other than rebate invoicing and verification." (Letter from Winona E. Rubin, Director, Department of Human Services, State of Hawaii, Re: State Plan Amendment # 92-08, to Mr. Lawrence L. McDonough, Associate Regional Administrator, Health Care Financing Administration, San Francisco, CA, May 13, 1992)

139. Second, the URA provided to the states under the drug rebate program cannot be reverse engineered to determine the AMP. The primary functions of the Medicaid Drug Rebate Program are carried out by CMS at the federal level. This federal rebate operation includes receiving the AMP and best price information from participating drug manufacturers, application of the inflation adjustment factor, and calculating a single value (URA) for each drug product for each quarter. This URA is the value provided quarterly to state Medicaid programs to multiply by their quarterly drug utilization volume to determine the rebate amount due from a drug manufacturer. The state's role in the Medicaid Drug Rebate Program is to track the state's drug utilization, to bill the drug

manufacturer for rebates, and to resolve any disputes over rebate amount that result from discrepancies in drug utilization.

140. Consistent with the statute, and related regulations and Medicaid Drug Rebate Program implementation procedures, the Secretary has not provided the state Medicaid programs with AMP values over time. The states were provided URAs and not AMPs. [60 Fed. Reg. 48442, 48475 (Sept. 19, 1995) (preface to proposed rule in 1995) (expressly discussing Secretary's limitation on access to AMP data by the states).

141. The URAs included the total amount per unit (e.g., tablet, capsule, or milliliter) due to Medicaid based on provisions of the rebate program including: the minimum rebate amount (i.e., AMP – 15.1%) and, if applicable, the best price rebate amount (AMP – best price), and the inflation adjustment amount. Because this URA incorporates multiple factors in a single number, including the minimum rebate amount, the best price rebate amount, and the inflation adjustment factor, it is not possible, on a reliable and consistent basis, for states to disaggregate the single number reported as a URA into the contribution made by each of the components. [*See* the CMS document titled "Unit Rebate Amount (URA) Calculation" found on May 15, 2008 at: http://www.cms.hhs.gov/MedicaidDrugRebateProgram/downloads/uracalc.pdf]. The URA is the only number provided to state Medicaid programs prior to the Deficit Reduction Act of 2005. With the passage of the DRA in 2005, Congress authorized provision of the AMP amounts for all covered drug products to states beginning in 2007. [DRA, Pub. Law 109-171 § 6001, 120 Stat. 4, 54 (2006)].

142. The URA for multisource non-innovator drug products was 11 percent of the AMP. While this single factor in the URA for a specific drug product could arguably, in

some cases, signal the AMP amount to states, this reverse engineering of the AMP was not permitted, as noted earlier, for any purpose other than collection of Medicaid rebates.[23] Furthermore, the AMP submitted to the Medicaid Drug Rebate Program by drug manufacturers is provided based on the 9-digit NDC code and not the 11-digit NDC code. Therefore, the AMP for an individual drug product at the 11-digit NDC code level cannot be reliably determined by reverse engineering AMP data provided at the 9-digit NDC level. Given the precision that states need to have in order to set reimbursement rates, this is not a reliable process to determine the payment amount for thousands of generic (multiple source) drug products.

143. Recall that every prescription drug product in the United States has a unique NDC number (11-digits) for each drug product marketed. This 11-digit number has three basic segments. The first segment (5-digits) uniquely identifies the drug firm and the second segment (4-digits) identifies the specific strength, dosage form, and formulation for a given drug product. The third segment (2-digits) identifies the package size and package type (e.g., bulk, unit dose, or unit of use). While products with the same 9-digit code are the same drug entity, dosage form, strength and manufacturer, there may be varying package sizes (e.g., 30 tablets v. 100 tablets v. 5,000 tablets) and varying package types (e.g., bulk bottle v. unit dose). The price of different package sizes and types may vary a little or a lot depending upon the drug firm, the drug product and the types of pharmacies or providers to which the drug manufacturer will sell each specific NDC or package type.

[23] Letter from Patrick J. O'Connell, State of Texas to Mr. Dennis Smith, CMS, March 31, 2003.

144. CMS has always asked drug manufacturers to report their AMP data at the 9-digit level based on the weighted average AMP across all related 11-digit NDCs. As noted by CMS in the Federal Register: "We agree that the AMP should continue to be weighted at the 9-digit NDC level, and retain this requirement in the final rule. CMS has used the weighted 9-digit AMP since the start of the rebate program and there is nothing in the statute or legislative history to indicate that the Congress meant for this to change when AMP is used for FULs."[24]

145. Just knowing the URA for a drug product does not mean that one knows the price that any given pharmacy paid or how many pharmacies could buy the drug product at or below that amount. The URA does not mean that one knows the underlying distribution of prices that made up that average manufacturer price. (e.g., see Jerry Wells, State of Florida, December 15, 2008, deposition in *U.S. ex rel. Ven-A-Care v. Abbott*, p. 260.)

146. Third, even if the statute did not prohibit disclosure or use, of AMP, or if determination of the AMP could be reverse engineered by the states, the use of AMP as a basis for estimated acquisition cost (EAC) or other reimbursement purposes was not practical for reasons which include the following: (1) AMP was not publicly available so that pharmacies and other providers would not know the amount they would be paid for providing prescription drugs; and (2) use of AMP-based reimbursement would have required a complete change of the entire Medicaid drug program's pharmacy reimbursement system and not just a minor adjustment to the existing system.

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[24] See CMS, Medicaid Program; Prescription Drugs, Final Rule, *Fed. Reg.*, July 17, 2007, p. 39215.

147. Pharmacies agree to provide prescription drugs to beneficiaries of state Medicaid programs based on a contract, and/or pricing information, that is available to the pharmacy prior to dispensing the prescription. If AMP were used for estimating acquisition cost (EAC) for reimbursement purposes—a use which was not permissible—the confidential nature of AMP would have created an uncertain business proposition for the pharmacies. Essentially, the pharmacies would be faced with a proposition from Medicaid which says, "if you agree to participate in the Medicaid program you will be paid the lower of an estimated acquisition cost based on AMP—a price which we cannot disclose to you—plus a dispensing fee, a federal upper limit (or maximum allowable cost, MAC) based on AMP plus a dispensing fee, or your usual and customary price to the general public." A pharmacy business is not likely to agree to provide prescriptions to Medicaid when they do not know the amount that will be reimbursed for the prescription until after the prescription has already been dispensed. This is not a reasonable business arrangement for the pharmacy.

148. Finally, the adoption and implementation of an AMP-based reimbursement system to pay pharmacies for prescriptions under Medicaid is not a simple administrative change. Instead, this shift would have required a complete change of the entire Medicaid drug program's pharmacy reimbursement system and not just a minor adjustment to the existing system. In fact, Congress passed the DRA to require, *inter alia*, a major change in the reimbursement system using AMP as a basis for setting federal upper limits for generic drugs. CMS published proposed rules and later final rules for implementing an AMP-based reimbursement system that would also have disclosed AMP prices to the public. For a variety of reasons, the CMS final rule and the

process by which it was promulgated was considered problematic by the community pharmacies. These pharmacy groups filed a motion for preliminary injunction to halt the execution of the AMP-based FUL reimbursement and the posting of those prices for the public.[25] The federal court granted this preliminary injunction in December of 2007 and I understand that this litigation is ongoing.

C. Prescription Reimbursement Under the State Medicaid Drug Programs

149. State Medicaid drug programs pay for prescription drugs provided to Medicaid enrollees through community pharmacies based on a method known as a 'lower of' formula. That formula, as described in the Medicaid regulations, and also routinely reported in the NPC Medicaid Book [NPC, *Pharmaceutical Benefits*, 1993, p. 15., and other annual volumes] states drug reimbursement or payment "is not to exceed the lowest of:"

- the maximum allowable cost (MAC) of the drug as established by HCFA's [now CMS's] pharmaceutical reimbursement board for certain multisource drugs (generic drugs), plus a reasonable dispensing fee;
- the estimated acquisition cost (EAC) of the drug (the price generally and currently paid by providers for a particular drug in the package size most frequently purchased by providers), as determined by the program agency, plus a reasonable dispensing fee; or
- the providers' usual and customary charge to the public for the drug.

150. CMS (formerly HCFA) regulations clearly state that the estimated acquisition cost is meant to be "as close as feasible to the price generally and currently paid by the provider. The states are, therefore, expected to set their ingredient cost levels as close as possible to actual acquisition cost." ["HHS Action Transmittal, HCFA-AT-77-113 (MMB), December 13, 1977. Subject: Title XIX, Social Security Act: Limitation on

[25] I have provided an expert report on behalf of Plaintiffs on November 13, 2007 in *National Association of Chain Drug Stores and National Community Pharmacists Association v. U.S. Department of Health and Human Services and Michael O. Leavitt, Secretary of HHS, and CMS, and Kerry Weems, Acting Administrator of CMS*, U.S. District Court for the District of Columbia, Case No. 1:07-cv-02017.

Payment or Reimbursement for Drugs: Estimated Acquisition Cost (EAC)" as reproduced in National Pharmaceutical Council (NPC), *Pharmaceutical Benefits Under State Medical Assistance Programs*, 1983, p. 14]. The state Medicaid programs are expected by CMS to meet this objective.

151. As noted earlier, this description of EAC emphasizing that this term is supposed to represent a price that is "as close as feasible to the price generally and currently paid by the provider" or a similar statement has been reported in every annual volume of the NPC Medicaid Book from 1979 to 2005-2006. Roxane was aware of, and had access to, this publication since Boehringer Ingelheim (a Roxane affiliate) has been a sponsoring member of the National Pharmaceutical Council since 1983 or before.

152. The state Medicaid approach to estimating acquisition cost—their best estimate of actual acquisition cost—relies upon data reported by manufacturers, pharmacies and other providers. As noted previously, the state Medicaid programs rely upon drug pricing information from drug manufacturers provided through a commercial drug price database, including AWP, WAC, and DP. The vast majority of state Medicaid programs rely primarily upon the AWP. The state Medicaid drug programs then use this information in a formula that determines the 'lower of': (1) the estimated acquisition cost, calculated based upon the price representations of drug manufacturers, plus the dispensing fee, (2) the MAC or FUL amount plus a dispensing fee, or (3) the pharmacy's usual and customary charge for the prescription as reported by the pharmacy.

153. Some state Medicaid drug programs determine the estimated acquisition cost based upon whether the pharmacy or provider can purchase the drug product directly from the manufacturer or through a wholesaler. If the pharmacy or physician purchases

the drug through a wholesaler, then the AWP or WAC, as reported by the drug manufacturer to the price database, is used to determine wholesale EAC. (e.g., see Brendan Joyce (ND), *U.S. ex rel. Ven-a-Care v. Abbott Lab, Inc.*, 06-11337-PBS, Dec. 12, 2008, pp. 243-247; and Roxanne Homar (WY), *U.S. ex rel. Ven-a-Care v. Abbott Lab, Inc.*, 06-11337-PBS, Dec. 3, 2008, pp. 397-398.) If the drug manufacturer sells its drug products directly to pharmacies or other providers, then the state Medicaid drug program may use the DP as the basis for determining payment for the ingredient cost of the prescription.

154. Additionally, the total amount of payment to pharmacies and providers for a prescription, or to DME providers for DME drugs, must be taken into account, including both the drug product cost payment and the dispensing fee payment. As noted in a research report to CMS [Wrobel, Schondelmeyer, et al., *Case Study of the Texas Vendor Drug Program,* 2005, p.67]:

> Stakeholders also agreed that, if the public sector did seek to improve the accuracy of its estimates of acquisition costs for use in Medicaid payment, then it would be absolutely essential to improve the accuracy of estimates of the cost of dispensing. Although many stakeholders acknowledged that current estimates of acquisition costs and the resulting drug product payment levels might be inflated, they also believed that current estimates of dispensing costs and Medicaid dispensing fees were too low. The combined effect of the two components of estimated cost (the drug product cost and the dispensing fee) is what ultimately determines payment and the financial performance of the retail pharmacy.

While the payer, Medicaid, may take into account a known drug product spread amount (such as the AWP to WAC spread) when establishing the reimbursement formula including the pharmacy dispensing fee or physician administrative fee, it is contrary to public policy for the amount of a spread to be hidden from the payer (i.e., the state Medicaid program) or to be manipulated by the drug manufacturer. For example, the Colorado Medicaid agency designee stated that he was not "aware of any policy or

practice of Colorado Medicaid to pay excessive reimbursement to cover any claimed inadequate dispensing fee." (Deposition of Allen D. Chapman, *U.S. ex rel. Ven-A-Care v. Dey et al.*, December 15, 2008, p. 331.) In addition, this Colorado Medicaid representative testified that he was aware of no information that "Colorado approved of drug companies incentivizing pharmacies based on Medicaid reimbursement." (Deposition of Allen D. Chapman, *U.S. ex rel. Ven-A-Care v. Dey et al.*, December 15, 2008, p. 343.)

155. The setting of payments for prescription drugs is also critical to providing access to prescriptions and pharmaceutical care. For example, the Medicaid program wants to ensure that enough pharmacy providers choose to participate so that patients will have access to the drug products they are prescribed within a reasonable distance from the patient's home or work.

156. Consequently, it is critical for the Medicaid system to have an accurate estimation of the cost of dispensing, as well as the amount that a pharmacy paid to acquire a drug product, so that the reimbursement can be set at the proper level. Every Medicaid program, and the federal Medicare program, has structured its reimbursement with separate components for dispensing (or administrative) fees and drug product (ingredient) cost reimbursement in order to permit the highest degree of control for the programs over each of those components. Plainly, however, even if a Medicaid program were to determine that it would be advantageous to set below-cost dispensing fees, and "make up" for the shortage by paying higher drug ingredient cost reimbursement, it would nonetheless be critical for the program to have accurate and reliable cost information in order to strike the proper balance that the program deemed appropriate and

to ensure that any reimbursement decisions were meeting the Medicaid program's objectives. (e.g., see Ayuni Hautea-Wimpee (WA), *U.S. ex rel. Ven-a-Care v. Abbott Lab, Inc.*, 06-11337-PBS, Nov. 24, 2008, p. 148; Brendan Joyce (ND), *U.S. ex rel. Ven-a-Care v. Abbott Lab, Inc.*, 06-11337-PBS, Dec. 12, 2008, pp. 241-244; and Allen Dale Chapman (CO), *U.S. ex rel. Ven-a-Care v. Abbott Lab, Inc.*, 06-11337-PBS, Dec. 2008, pp. 323-324.)

157. I have been asked to address the following assertions by Roxane:

> ". . . During the pertinent period alleged in the complaint, the public record [ ] demonstrates that the Government was well aware that the prices reported by third party-publishers were not actual acquisition cost, but rather reflected undiscounted "list" prices. [ ] In addition, the public record shows that Congress resisted lowering reimbursement formulas to advance various policy goals, including ensuring patient access to medical care and cross-subsidization of other costs incurred by health care providers participating in the programs. [ ] Thus, the government has known for decades that the drug prices published by third-party publishers do not reflect actual acquisition costs, but none the less chose to continue reimbursing above acquisition costs to further specific policy goals." (Roxane's Memorandum of Law In Support of Its Motion to Dismiss, Filed March 22, 2007, pp. 6-7 and footnote 4 on page 6.)

These assertions by Roxane are not consistent with, and are in direct opposition to, long standing Medicaid statutes, regulations, policies and practices. The following paragraphs in this section, and throughout my report, describe and explain how these assertions are not supported.

158. I have also been asked to address Dey's assertion that:

> ". . . The reports, moreover, provide that the States favored using AWPs for policy reasons, such as allowing a spread to encourage Providers to participate in the State Medicaid programs and compensate pharmacies for inadequate dispensing fees." (Dey's Memorandum of Law In Support of Its Motion to Dismiss, Filed December 22, 2006, p. 11.)

Dey's premise that states "favored using" inflated AWPs for policy reasons is not consistent with, and is in direct opposition to, long standing Medicaid statutes, regulations, policies and practices. The following paragraphs in this section, and throughout my report, describe and explain how these assertions are not supported.

159. As noted elsewhere in this report, the Medicaid regulations clearly state that the estimated acquisition cost is meant to be "as close as feasible to the price generally and currently paid by the provider. The states are, therefore, expected to set their ingredient cost levels as close as possible to actual acquisition cost." ["HHS Action Transmittal, HCFA-AT-77-113 (MMB), December 13, 1977. Subject: Title XIX, Social Security Act: Limitation on Payment or Reimbursement for Drugs: Estimated Acquisition Cost (EAC)" as reproduced in National Pharmaceutical Council (NPC), *Pharmaceutical Benefits Under State Medical Assistance Programs*, 1983, p. 14]. Roxane and Dey knew the purpose of the Medicaid program and the method used to estimate acquisition cost. Instead of reporting prices "as close as feasible to the price generally and currently paid by the provider", however, Roxane and Dey knowingly reported and continued to report prices that were not close to the prices actually paid and even lowered their actual prices while at the same time they raised their reported prices to influence the payments to providers and the sales of their drug products.

160. Some Medicaid officials did become aware that published AWPs were not the pharmacy's actual acquisition cost. This awareness may have come from Medicaid audits, OIG studies, and GAO studies that selectively examined the relationship of AWP to actual invoice prices paid by pharmacies. The state Medicaid programs understood and expected that there was a known relationship between AWP and pharmacy invoice

prices such that an estimated acquisition cost (EAC) could be determined by AWP minus a certain percentage or WAC plus a certain percentage. All state Medicaid programs did adopt EAC procedures that were based on the known relationship of AWP to WAC (i.e., AWP is 20 to 25 percent above the WAC, or WAC is 16.67 or 20 percent below AWP, previously noted). This difference between the AWP and WAC can be referred to as the AWP-WAC spread or the formulaic spread.

161. When pharmacy actual acquisition prices have been selectively studied, they have sometimes been found to be substantially below the reported prices, and this is especially so for generic or multisource drug products. As described elsewhere in this report, some multisource and generic drug products will have AWPs that are the typical 20 to 25 percent above the WAC, but it is not unusual to see generic drug products with an AWP that is 50 to 100 percent, or more, above the WAC. Drug manufacturers with multisource or generic drug products usually lower their actual transaction prices due to price competition from other multisource drug products, but their reported prices (AWP and WAC) typically remain the same or even, in some cases, increase. Roxane and Dey have engaged in such pricing conduct as described elsewhere in this report. The spread between AWP and actual prices or between WAC and actual prices is known as the EAC-AAC (actual acquisition cost) spread or, sometimes as the mega-spread because these spreads can be as much as 30 percent to more than 1000 percent above the actual price. In fact, in the relevant time period, Roxane created and used mega-spreads that ranged from 208% to 1,405% for 32 specific drug products named by the United States in this case [see Exhibit B of The United States' First Amended Complaint, *U.S. ex rel. Ven-A-Care v. Boehringer Ingelheim et al.*, December 2, 2008]. During the calendar year

2001, Dey created and used mega-spreads that ranged from 203% to 630% for 13 specific drug products named by the United States in this case [see Exhibit A of The United States' First Amended Complaint, *U.S. ex rel. Ven-A-Care v. Dey et al.*, September 29, 2008].

162. The state Medicaid programs expected that the manufacturer prices reported to the price databases were based on actual or transaction prices, or based on the known relationship to actual prices. In cases where Medicaid or others conducted an audit of invoices, the auditors expected that the manufacturer and wholesaler prices on invoices to pharmacies were actual prices. Medicaid administrators were not aware that certain manufacturers, such as Roxane and Dey, inflated these prices (AWP, WAC, DP or other prices found on invoices) to increase their sales, to increase reimbursement to pharmacies, or to distort the expected relationships to actual prices at any point in time or over time.

163. Even if certain state Medicaid programs were to have taken into account a known drug product spread amount (such as the AWP to WAC spread) when establishing the pharmacy dispensing fee or DME administrative fee, it undermines the policy objectives of the program for the amount of a spread to be hidden from the payer (i.e., the state Medicaid program) or to be manipulated by the drug manufacturer unbeknownst to the Medicaid program. To the extent that a drug product cost spread exists, and is known to Medicaid, the Medicaid program could have adjusted EACs or dispensing fees, but such a payment policy is the purview of Medicaid and not drug manufacturers. In order to be able to make such payment decisions, Medicaid assumes, and depends upon, accurate and reliable price information from manufacturers in order to strike the proper

balance that the program may deem appropriate and to ensure that any reimbursement decisions meet the Medicaid program's objectives. (e.g., see Roxanne Homar (WY), *U.S. ex rel. Ven-a-Care v. Abbott Lab, Inc.*, 06-11337-PBS, Dec. 3, 2008, p. 423.)

D. Federal Upper Limits (FULs) and Maximum Allowable Costs (MACs)

164. The Medicaid payment formulae include maximum allowable cost provisions. There are two basic types of maximum allowable costs (MACs): (1) federal MACs, also known as federal upper limits (FULs) and (2) state MACs. However, not all generic drug products have either a federal or a state MAC.

165. Whether or not a FUL is set by the federal Medicaid program is not up to the 'belief' of the Medicaid program about the appropriateness of prices for generic drug products. Specific criteria are stated that will trigger whether or not a FUL may be established. Prior to the DRA [Deficit Reduction Act of 2005, Pub. Law 109-171 § 6001, 120 Stat. 4, 54], FULs were established only when three or more 'therapeutically equivalent' drugs (in the same drug product group) were on the market.[26] The final rule for the DRA (2007) changed that requirement so that an FUL will be established when therapeutic equivalence has been determined for only "two or more" drug products.[27] The "FUL is now to be set when at least two suppliers (e.g., manufacturers, wholesalers, re-packagers, or re-labelers) list the drug in a nationally available pricing compendia

[26] The term 'therapeutically equivalent drugs' is used in the proposed rules to mean "drugs that are identified as A-rated in the current edition of the FDA's publication, "*Approved Drug Products with Therapeutic Equivalence Evaluations*" (including supplements or successor publications)." See CMS, Medicaid Program; Prescription Drugs, Final Rule, Fed. Reg., July 17, 2007, p. 39154.

[27] The statute reads, "the Secretary shall establish a Federal upper reimbursement limit for each multiple source drug for which the FDA has rated three or more (or, effective January 1, 2007, two or more) products therapeutically and pharmaceutically equivalent, regardless of whether all such additional formulations are rated as such and shall use only such formulations when determining any such upper limit." [42 U.S.C. §1396r–8(e)(4). Payment for covered outpatient drugs].

(e.g., *Red Book*, *First DataBank*, or *Medi-Span*)."[28] Thus, the number of drug product groups that will have FULs under the new DRA provisions will be substantially broadened from the previous number of FULs.

166. Not all generic, or off-patent, drug products have federal FULs or state MACs. Prior to the DRA, there were about 500 drug product groups with an established FUL. Under the new rule issued to implement the DRA, the number of drug product groups with FULs was expected to grow to 3,000 or more.[29] Minnesota has State MACs or FULs for 734 drug product groups and Washington has about 1,400 drug product groups with State MACs or FULs. Even the state with the most aggressive State MAC program (Washington) has state MACs for only about one-half of more than 3,000 drug product groups expected to have FULs under the final DRA rule.[30]

167. Certain multisource drug products have FULs and some do not, and among those that do not have FULs some may have state MACs and others do not. In California, for example, the Medi-Cal (state Medicaid) program sets MAICs (maximum allowable ingredient cost) which are upper limits for payment of the drug ingredient cost that are well below the list prices for a drug product.

168. Even today, when states have become more aggressive with MACs, state-negotiated rebates, and other forms of cost containment, a large proportion of the generic drug products do not have MACs or FULs. To illustrate the relative proportion of

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[28] See CMS, Medicaid Program; Prescription Drugs, Final Rule, Fed. Reg., July 17, 2007, p. 39155.

[29] Analysis of data on FULs, state MACs, commercial MACs, and other pricing data provided through personal communication with George Saunders, Pharm.D., Vice President, Professional Services, AmeriSourceBergen, e-mail on June 28, 2006 and an excel file titled "FUL vs Comm MAC vs State MAC 10052005.xls".

[30] Minnesota Medicaid has 734 drug product groups with State MACs which includes the 496 drug product groups with federal FULs. The number of State MACs in Minnesota compared to other states ranks 24th with the largest number of State MACs being nearly 1,400 in Washington. See George Saunders, AmeriSourceBergen, e-mail on June 28, 2006 and excel file titled "FUL vs Comm MAC vs State MAC 10052005.xls".

multisource products with and without MACs (or FULs), actual data from Medi-Cal was examined for 2006. The number of prescriptions and the amount of drug expenditures for the Medi-Cal drug program were categorized by their patent status and by the presence or absence of an FUL. Single source brand name drug products were 27.5 percent of the prescriptions, but accounted for 66.6 percent of the drug program expenditures. Nearly three-fourths (72.4 percent) of the prescriptions were for multisource drug products and one-half of those multisource drug products had FULs while the other one-half did not. Expenditures for multisource generic drugs without FULs represented 21 percent of the total drug expenditures, and multisource generic drugs with FULs represented 12.4 percent of total drug expenditures.[31]

VII. THE MEDICARE PART B PROGRAM

169. The Medicare program began in 1965 and provides health care to the elderly, disabled, and others in the United States. Medicare provides inpatient (hospital) care under the Part A program and outpatient physician and diagnostic services through the optional Part B program. Part B also includes coverage of prescription drugs that are administered in the outpatient clinic or physician's office, as well as in connection with DME.

A. Medicare Part B Drug Program

170. Medicare Part B covers drugs that are "incident to" a physician's service, DME drugs, and drugs specifically covered by statute (for example, oral immunosuppressive drugs). Part B drug expenditures grew from $3.3 billion in 1998 to

[31] Myers and Stauffer, *Survey of Dispensing and Acquisition Costs of Pharmaceuticals in the State of California*, December 2007, pp.36 and Table 4.1.

$8.4 billion in 2002—a two and one-half fold increase in four years. Payment methods and both pricing and utilization trends for specific drugs within the Medicare Part B drug program have contributed to the growth in drug program expenditures.

171. From 1991 to 1998, the method of payment for drugs under Medicare Part B was based on the lower of: (1) estimated acquisition cost or (2) national average wholesale price for a drug. If a drug was available from multiple sources, the payment was based on the median of the national average wholesale prices for generic equivalents. EACs were defined as the "actual invoice prices paid by the providers furnishing the drug" and were to be determined based on provider surveys.[32] In addition to the drug cost, the survey was to include indirect costs such as inventory, waste, and spoilage. In practice, the Medicare administrative contractors set the payment limit at AWP according to the Red Book or First DataBank's Blue Book. The statutory basis for Medicare drug payments changed to AWP minus 5 percent beginning on January 1, 1998.[33]

172. In contrast, in the early 1990s the Medicaid program was using EAC, defined by most states as AWP minus 'X' percent, with the reduction to AWP ranging from 5 to 15 percent.

173. Another change known as 'least costly alternative' (LCA) was developed through certain Medicare administrative contractors as early as mid-1997. The LCA approach reasoned that when there were two or more similar or equivalent therapeutic

[32] Department of Health and Human Services, Health Care Financing Administration, "Medicare Program; Fee Schedule for Physicians' Services," Fed. Reg., Nov. 25, 1991, 59502-59524.
[33] Health Care Financing Administration, Program Memorandum (Intermediaries/Carriers), HCFA Pub. 60AB, transmittal No. AB-97-25 Jan. 1, 1998, "Medicare: Payments to Providers, Part B payments—Physician fee schedule—Drugs"; see also, Health Care Financing Administration, Program Memorandum (Intermediaries/Carriers), HCFA Pub. 60AB, transmittal No. AB-98-76 Dec. 1, 1998, "Medicare: Part B Participation, Practitioner and outpatient services—Drugs and biologicals".

alternatives, the Medicare Part B payment could be limited to the cost of the least costly alternative. This LCA approach started in just a few states, but by 2002 had spread to Medicare administrative contractors servicing more than 40 states.

174. Beginning January 1, 2004, the payment amount for drugs administered by physicians was revised based on statutory language contained in the Medicare Prescription Drug, Improvement, and Modernization Act (MMA; Pub.L. 108-173). The new payment method was to be 85 percent of the AWP as of April 1, 2004 for most physician-administered drugs with certain exceptions. The MMA further described payment rules to be implemented January 1, 2005 based on manufacturer submission of data on a drug's average sale price (ASP). The specific payment amount is 106 percent of the ASP.

175. The ASP is defined in the MMA as the amount of the manufacturer's sales revenue to all purchasers divided by the total number of units sold in a given quarter. The manufacturer should include the effect of "volume discounts, prompt pay discounts, cash discounts, free goods that are contingent on any purchase requirement, chargebacks, and rebates (other than rebates under the Medicaid program)."[34]

176. At the same time that the MMA altered its payment policy for the drugs covered by Part B, it also specified new procedures for calculating the practice expense relative value units (RVUs) associated with drug administration services for certain physician specialties and for clinical oncology nurses.[35] There was also a provision that specified new procedures for establishing the dispensing fees for administration of

[34] Department of Health and Human Services, Centers for Medicare and Medicaid Services, "Medicare Program; Changes to Medicare Payment for Drugs," Fed. Reg., Jan. 7, 2004, 1084-1116.
[35] Department of Health and Human Services, Centers for Medicare and Medicaid Services, "Medicare Program; Changes to Medicare Payment for Drugs," Fed. Reg., Jan. 7, 2004, 1084-1116.

nebulizer medications. (CMS, CSR Inquiry Assistance, "Supplying Fee and Inhalation Drug Dispensing Fee Revisions and Clarifications," found on January 21, 2009 at: http://www.cms.hhs.gov/ContractorLearningResources/downloads/JA3990.pdf.)

B. Sources of Growth in Medicare Part B Drug Expenditures

177. There has been rapid growth in Medicare Part B drug expenditures since the mid-1990s. Analysis of the sources of this growth reveals that only a few of the approximately 450 covered drugs account for most of the spending. As noted earlier, drug expenditures in 1998 were about $3.3 billion and this amount grew to more than $8.4 billion by 2002.[36] During the same period (1998 to 2002), the Medicare enrollment grew only 1.4 percent per year, while the drug spending grew an average of 27 percent per year. The vast majority (77 percent) of the Medicare Part B drug expense is paid to oncologists and urologists. Oncologist-based drug expenditures grew from $1.2 billion in 1998 to $3.8 billion in 2002, with the spending growth from 2001 to 2002 at 41 percent.

178. The spending on drugs under Medicare Part B is highly concentrated, with 7 of the approximately 450 drugs accounting for 49 percent of the spending ($4.0 billion out of $8.4 billion in 2002). Nineteen drugs accounted for 75 percent of the total drug expenditures and 33 drugs accounted for 86 percent of the total. Both increases in manufacturer reported prices and increases in utilization appear to have been the major contributors to growth in drug expenditures for the Medicare Part B program.

[36] Department of Health and Human Services, Centers for Medicare and Medicaid Services, "Medicare Program; Payment Reform for Part B Drugs; Proposed Rule," Fed. Reg., Aug. 20, 2003, 50428-52.

C. Payment for DME Drugs

179. Along with colleagues at Abt Associates, Inc., I conducted a study for CMS on the payment for drugs related to Medicare Part B.[37] This payment method is essentially the same as that used for DME drugs by the many state Medicaid drug programs. A brief summary of the J-code methodology is described here:

> A HCPC is a grouping code for drug products (at the NDC-11 level) that have the same chemical entity and dosage form that can be used to deliver a specific amount of medication. Each unique dosage form, strength, and package size of a drug produced by each manufacturer is assigned a unique NDC-11 number.

180. J-codes are a specific type of HCPC (Healthcare Common Procedure Code) for prescription drugs covered under Medicare Part B. The payment rate for these drugs is established by the Medicare carrier (or fiscal intermediary) for a specific region of the country based upon the median of an array (as compiled by the Medicare fiscal intermediary) of AWPs published in the Red Book for NDCs identifying the same drug product and delivering the same dose. State Medicaid drug programs may also pay for certain drugs that are physician-administered. Physicians, or other providers such as DME providers and home infusion pharmacies, are reimbursed for providing these drugs to Medicaid recipients based upon payment rates established for all drug products within a specific 'J-code.'

181. During the time period at issue in this case, the payment rate for a J-code was set based upon the median AWP per unit from an array, as compiled by the Medicare carriers, of drug products (at the 11-digit NDC level) that can be used to provide the defined dosage unit for that J-code.

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[37] Wrobel, Marian V., Stephen W. Schondelmeyer, Susan Jureidini, Shuchita Agarwal, Rachel Sayko, A.C. Doyle, *Sales of Drugs and Biologicals to Large Volume Purchasers: Final Report*, CMS Contract #500-00-0049, Task Order 1, September 19, 2005.

182. The reporting of an inflated AWP for one or more NDCs within a J-code group by a drug company could lead to an inflated median for that J-code that would affect the payment amount for all manufacturers' drug products reimbursed under that J-code. If instead, a manufacturer reported a price, or AWP, based on actual sales to wholesalers or to direct purchasers, the published truthful AWP for each of the manufacturer's drug products may have resulted in a lower median price leading to lower payments.

183. A drug manufacturer's failure to report truthful prices may affect the reimbursement for all prescriptions paid based upon a J-code that includes one or more of that manufacturer's drug products, regardless of whose drug product was actually provided to the Medicare or Medicaid patient.

VIII. IMPORTANCE OF MEDICAID AND MEDICARE TO PHARMACEUTICAL MANUFACTURERS AND OTHER TOPICS

184. The Medicaid program is very important to pharmaceutical manufacturers. Medicaid prescription expenditures have accounted for 8% to 15% of total U.S. outpatient prescription dollars over the past 15 years (i.e., 1991 to 2005) and Medicaid paid for 8% to 14% of the total number of outpatient prescriptions dispensed in the United States over the past 15 years (i.e., 1991 to 2005). For manufacturers like Dey and Roxane whose drug products were sometimes administered in conjunction with DME, the Medicare program was an important source of reimbursement.

185. As noted earlier in this report, up until January of 2006, the Medicaid drug program was the single largest outpatient drug program in the United States.

186. Medicaid is also important to pharmaceutical manufacturers because their pricing behavior in the broader pharmaceutical market may affect the rebates that must be paid under the voluntary agreement with the Secretary of the Department of Health and Human Services to enable participation in the national Medicaid Drug Rebate Program.

187. The Medicaid program and the operational details of drug coverage and reimbursement on a state-by-state basis, as well as Medicare reimbursement for drugs under Part B, are essential information for key personnel at every pharmaceutical manufacturer. This coverage and reimbursement information is important for persons working in business strategy, pricing, product management, marketing, and other units.

188. Medicaid is so important that pharmaceutical manufacturers support the compilation of detailed Medicaid drug program information and experience on an annual basis. Drug companies also engage in lobbying activities related to federal and state legislative and regulatory actions that may influence access to their drug products and the amounts providers are reimbursed for these drug products by Medicaid, Medicare, or other government programs.

A. The National Pharmaceutical Council and the NPC Medicaid Book

189. The National Pharmaceutical Council (NPC) is a group of pharmaceutical companies "engaged in the discovery, development, production, and marketing of innovative prescription medicines." The National Pharmaceutical Council, Inc. was founded in 1953 and in 1992 had twenty-nine member companies. The 2005/2006 version of the NPC Medicaid Book lists twenty member companies on its back page. The membership includes some new firms, but the number of members has declined over time due, in part, to many mergers and acquisitions among drug firms.

190. BIPI is currently a member of NPC and has been a member for more than 27 years, since at least 1980.[38]

191. The Medicaid drug program is so important that the NPC publishes an annual volume titled "Pharmaceutical Benefits Under State Medical Assistance Programs" (known as the NPC Medicaid Book). A "Dear Reader" letter in the preface to the 1992 edition of this publication says, "Since 1965, it has been published by the National Pharmaceutical Council to support your evaluation of Medicaid program characteristics." [NPC Medicaid Book, 1992]. The NPC Medicaid Book was first published in 1965 and continues to be published every year. The 2005/2006 edition marked the 40th annual volume of the NPC Medicaid Book.

192. The NPC Medicaid Book is compiled from data obtained from the Health Care Financing Administration (now the CMS), from a survey of "state Medicaid program administrators and consultants," and from other federal agencies and organizations. [National Pharmaceutical Council, *Pharmaceutical Benefits Under State Medical Assistance Programs*, 1992, p.iii]. The NPC Medicaid Book preface in the form of a "Dear Reader" letter explains that NPC "provides services to pharmacists, manufacturers, professional associations, colleges of pharmacy, physicians, medical schools, government offices, and consumers concerning key aspects of health care."

193. As noted in the *Introduction*, the NPC Medicaid Book "has become a standard reference and invaluable resource in government offices, research libraries, consultancies, the pharmaceutical industry, numerous businesses, and policy organizations." [NPC Medicaid Book, 2005/2006, p. 1-3].

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[38] The back cover of the NPC's annual volume of *Pharmaceutical Benefits Under State Medical Assistance Programs* lists the member companies and, prior to 1983, the NPC letterhead listed the member companies.

194. The NPC Medicaid Book is updated every year and profiles each state's Medicaid program and related policies. The NPC Medicaid Book also contains information on all states, as well as the District of Columbia.

195. The NPC Medicaid Book makes clear the extent to which Medicaid relies upon published prices. This book also contains the following types of information: (1) an overview of the Medicaid program, its history, and related regulations; (2) socio-demographic statistics, by age, race, insurance, income, and employment, for the fifty states and the District of Columbia; (3) Medicaid pharmacy program characteristics, drawn largely from the annual survey of state pharmacy program administrators and Medicaid pharmacy program characteristics, such as total expenditures, drug payments, drug benefit design, and pharmacy payment and patient cost sharing; (4) detailed profiles of the states' Medicaid pharmacy programs and a description of medical assistance benefits and eligibles, drug payments and recipients, benefit design, pharmacy payment and patient cost sharing, use of managed care, and state contacts; (5) profiles of State pharmaceutical assistance programs, for those states with such programs; (6) a list of state contacts, CMS regional offices and Medicaid program personnel; (7) a national level summary on total Medicaid program recipients by type of service; (8) data on total number of drug recipients for each state and the nation; (9) provisions of the current Medicaid drug rebate law; (10) the list of CMS federal upper limits on multiple source products; and (11) a glossary and list of acronyms.

196. The size and importance of the Medicaid program is so great that any key person in an area such as marketing, pricing and reimbursement, product management, or business strategy at a pharmaceutical company would have to be aware of the payment

policies of Medicaid, or at least of where to find information on such policies. Key Roxane and Dey personnel would have been aware of the NPC Medicaid Book and most probably had a copy of the book in their offices.

B. Price Disclosures of Relator

197. Until the efforts and disclosures of Ven-A-Care, I am not aware of any government or other published study or report that documented the inflation and manipulation of prices reported by certain drug manufacturers. Ven-A-Care's disclosures of reported price manipulation and inflation by drug manufacturers, such as Roxane and Dey, were initially provided in August of 1995 and led to government investigations and litigation.

198. I am familiar with Ven-A-Care's 1997 presentation to Texas Medicaid and the Texas Office of the Attorney General. Also, I am familiar with the 2000-2001 investigation led by Congressman Pete Stark and the House Committees on Energy and Commerce and Ways and Means, including the information provided by Ven-A-Care pursuant to the Commerce Committee's subpoena. As an expert in pharmaceutical economics for more than 30 years, it is my opinion that the information provided by Ven-A-Care to these entities and other governmental bodies was significant in illuminating certain drug manufacturer pricing and marketing activities. This type of information was not typically made available, or provided by, pharmaceutical manufacturers to anyone in the marketplace. The Ven-A-Care revelations eventually enabled the government to understand the role of specific conduct by certain drug manufacturers and how such activities led to a detrimental impact on Medicare and Medicaid reimbursement rates and program expenditures.

199. A sampling of government studies conducted subsequent to the disclosures of Ven-A-Care is listed below:

a. Brown, June Gibbs. Appropriateness of Medicare Prescription Drug Allowances. Department of Health and Human Services, Office of Inspector General, May 1996.OEI-03-95-00420;

b. Brown, June Gibbs. Suppliers' Acquisition Costs for Albuterol Sulfate. Department of Health and Human Services, Office of Inspector General, June 1996.OEI-03-94-00393;

c. Brown, June Gibbs. Excessive Medicare Payments for Prescription Drugs. Department of Health and Human Services, Office of Inspector General, December 1997.OEI-03-97-00290;

d. Brown, June Gibbs. Need to Establish Connection between the Calculation of Medicaid Drug Rebates and Reimbursement for Medicaid Drugs. Department of Health and Human Services, Office of Inspector General, May 1998, OEI-03-97-00052;

e. Brown, June Gibbs. The Impact of High-Priced Generic Drugs on Medicare and Medicaid. Department of Health and Human Services, Office of Inspector General, July 1998.OEI-03-97-00510;

f. Medicare Reimbursement of Prescription Drugs. Department of Health and Human Services, Office of Inspector General, January 2001.OEI-03-00-00310;

g. Rehnquist, Janet. Medicaid's Use of Revised Average Wholesale Prices. Department of Health and Human Services, Office of Inspector General, September 2001. OEI-03-01-00010;

h. Rehnquist, Janet. Medicaid Pharmacy-Actual Acquisition Cost of Brand Name Prescription Drug Products. Department of Health and Human Services, Office of Inspector General, August 2001. A-06-00-00023;

i. Rehnquist, Janet. Medicaid Pharmacy- Actual Acquisition Cost of Generic Prescription Drug Products. Department of Health and Human Services, Office of Inspector General, March 2002. A-06-01-00053;

j. Rehnquist, Janet. Medicaid Pharmacy- Additional Analyses of the Actual Acquisition Cost of Prescription Drug Products. Department of Health and Human Services, Office of Inspector General, September. A-06-02-00041; and

k. Myers and Stauffer LC. Prepared for the Texas Health and Human Services Commission. Determination of the Cost of Dispensing Pharmaceutical Prescriptions for the Texas Vendor Drug Program. August 2002.

D. Government GAO and OIG Studies

200. Academic and government researchers have not had ongoing or reliable access to pharmaceutical manufacturers' actual prices, or detailed information about marketing tactics, such as those disclosed by Ven-A-Care. This type of information would be essential to a determination of whether an individual drug company has reported prices that varied from those prices which would be consistent with the expected relationship of AWP to WAC. OIG and GAO reports have consistently validated this WAC to AWP relationship, since the WACs for drugs representing the majority of dollars expended for Medicaid reimbursement have historically been within 20% of AWPs.

201. The federal and state governments, including the U.S. Congress, have repeatedly attempted to study the relationship between drug prices published by price publishing services and the range of prices generally and currently paid by prudent purchasers in the marketplace. These OIG and GAO reports showing differences between the prices published in the drug price databases (AWP, WAC, and DP) and actual audited invoice prices by design covered a limited time frame, focused on a limited set of drugs and a limited set of providers in the sample, and presented simple and weighted averages or high to low price ranges that are not generalizable to all drug products at all points in time for all purchasers. The limited data from these government studies was not sufficient to routinely determine that there were substantial differences between the published benchmark prices (AWP, DP, and WAC) and the actual invoice prices to pharmacies and other providers.

202. These GAO and OIG studies were designed to look at very focused and certain pricing issues for specific drugs that were already known, or suspected. These studies were not designed to look for new, or unknown, pricing issues or marketing practices in general. Additionally, these GAO and OIG studies focused on pricing issues related to the formulaic spread (i.e., AWP to invoice price) and not the hidden spread from WAC (or invoice price) to actual acquisition cost.

203. An additional limitation to these studies was the lack of transaction price information from drug manufacturers and other participants in the market. The GAO and OIG did not usually have the full cooperation of drug manufacturers or providers in providing access to transaction level pricing data. In the limited instances where transaction price data has been available to the government or academic researchers, this data has been restricted in use and labeled as 'proprietary and confidential' by drug manufacturers.

204. These government studies were not designed to identify the reasons for the larger variances that were noted in the reports. Also, the government studies did not differentiate between variances that resulted from the activities of specific drug manufacturers rather than the existence of a large range of prices paid by prudent purchasers.

205. Government reports (i.e., GAO and OIG) that studied the price variances which appear in the market typically have shown the price difference to be bigger, on a percentage basis, for generics than for brands. These reports were not designed to look for, and did not uncover, the fact that some companies inflated reported prices for certain "brand" drugs.

206. No one study or set of isolated studies focused only on comparison of drug product prices would be sufficient to select, establish, or operate an entirely new system for setting reimbursement rates for prescriptions under the Medicaid or Medicare drug program on a comprehensive and ongoing basis across time. Simply knowing an "average" difference between published AWPs and invoice prices for a certain set of drug products at one point in time would not be sufficient to implement an ongoing reimbursement system that used an across the board discount off of AWP to pay pharmacies for providing prescriptions to Medicaid recipients.

IX. SUMMARY

207. The Medicaid drug reimbursement system is based upon the consistently stated intention of reimbursing for drug products at their actual price, that is a price "as close as feasible to the price generally and currently paid by the provider" – a concept referred to in Medicaid program regulations and policies as 'estimated acquisition cost.' The Medicare Part B payment system has also used a drug reimbursement formula that was based on 'estimated acquisition cost.'

208. Third party drug reimbursement systems, including Medicare and Medicaid, depend upon current and accurate price information reported directly by drug manufacturers to the commercial drug price database publishers. The payment systems of Medicare and Medicaid have relied upon prices reported by drug manufacturers, including Roxane and Dey, to the commercial drug price databases as the basis for determining the estimated acquisition cost and for setting specific reimbursement amounts for individual prescriptions.

209. Actual transaction prices are not readily available for private or public third party payers (including Medicare and Medicaid) to use as a basis for setting specific reimbursement amounts for individual prescriptions. The actual prices of drug manufacturers are considered by the manufacturers to be proprietary and confidential and are not made public.

210. The AMP was created to implement the Medicaid drug rebate program, but it was not created to serve as a payment and reimbursement system. The statute and regulations related to AMP prohibit the use of AMP for any purpose other than implementation of the drug rebate program.

211. There is no readily available substitute for the commercially published prices (i.e., AWP, DP, and WAC) widely used for payment and reimbursement systems by third party programs.

212. Roxane and Dey reported prices to the commercial drug price databases that were inflated in relation to actual drug prices. When Roxane and Dey reported inflated prices to the commercial drug price databases, those inflated prices resulted in the Medicaid and Medicare programs paying more than they otherwise would have paid for a given prescription. These payments resulted in Medicare and Medicaid spending more of the federal and state government resources than they otherwise would have spent for these drug products.

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